K053319

MAR 6 2006

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of ALLOMATRIX® Custom Putty.

Submitted By:	**Wright Medical Technology, Inc.**
Date:	November 18, 2005
Contact Person:	**Brian J. Young** Sr. Director, Regulatory Affairs
Proprietary Name:	**ALLOMATRIX® Custom Putty**
Common Name:	Bone Void Filler
Classification Name and Reference:	Filler, Calcium Sulfate Preformed Pellets – Class II, 888.3045
Device Product Code and Panel Code:	Orthopedics/MQV

DEVICE INFORMATION

A. INTENDED USE

ALLOMATRIX® Custom is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. ALLOMATRIX® Custom is intended to be gently packed into bony voids or gaps of the skeletal system as a bone graft extender (spine) and as a bone void filler in the extremities and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

B. DEVICE DESCRIPTION

ALLOMATRIX® Custom Putty is provided in the form of a kit with a premeasured powder and CBM chips, premeasured mixing solution, and the tools necessary to mix the components. After the powder is hydrated using all the mixing solution supplied in the kit (or BMA and local bone when used in the spine), the resultant putty can then be handled and placed in the appropriate bone voids. This product is supplied sterile for single patient use.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

ALLOMATRIX® Custom Putty was found to be substantially equivalent to the predicate devices. The safety and effectiveness of ALLOMATRIX® Custom Putty is adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

Osteoinductivity Potential

Each lot of Demineralized Bone Matrix (DBM) incorporated into ALLOMATRIX® Custom is evaluated *in vitro* using a surrogate cell-based assay[1]. The bioassay measures the proliferation of Saos human osteosarcoma cells in the presence of human DBM compared to positive and negative controls (osteoinductivity index)[1]. Results from this bioassay were correlated to the athymic rat model[2] and to clinical results of assayed DBM alone[1].

Or

Each lot of DBM incorporated into ALLOMATRIX® Custom is assayed *in vitro* for a native protein as a surrogate test marker for osteoinductive potential[3]. Results from this immunoassay were correlated to the athymic rat model for the DBM alone and the ALLOMATRIX® Putty[3]. Although only one native protein is used as the test marker, it is the combination of various proteins that is responsible for its osteoinductive potential.

Testing each lot of DBM with this cell-based bioassay[1] or immunoassay[3] assures that only DBM with osteoinductive potential is used in the ALLOMATRIX® Custom. The combination of DBM, Cancellous Bone Matrix (CBM), and binding medium has not been evaluated for osteoinductivity; therefore, it is unknown to what extent the formulation components may alter the osteoinductive character of the DBM. Additionally, it is unknown how osteoinductivity of the DBM component, measured via the *in vitro* bioassay[1] or immunoassay[3], will correlate with human clinical performance of ALLOMATRIX® Custom.

1. Wilkins, R.M. (1999) Clinical Effectiveness of Demineralized Bone Matrix Assayed in Human Cell Culture *Advances in Tissue Banking*. 3:113-124.

   This study correlated the results from the *in vitro* bioassay to results in the athymic rat model and clinical results of the DBM.

2. Lindholm TS, Urist MR. A quantitative analysis of new bone formation by induction in composite grafts of bone marrow and bone matrix. Clin Orthop 1980 Jul-Aug;(150):288-300.

3. Data on file at Wright Medical Technology, Inc.

Viral Inactivation Validation

The method for processing the DBM and CBM contained in ALLOMATRIX® Custom Putty was evaluated for its viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes, and genomes were evaluated. The viral inactivation testing demonstrated suitable viral inactivation potential of the processing method for a wide spectrum of potential human viruses.

Product Performance Testing

Clinical performance of the subject device mixed with BMA and local bone was evaluated by a comparison of radiographic outcomes (i.e., Lenke fusion score), SF-36 subjective questionnaire, Oswestry disability questionnaire, Visual Analog Scale for back and leg pain, and adverse event profile compared to autograft iliac crest bone. This study demonstrated equivalency between the subject device and predicate autologous iliac crest bone where lumbosacral fusion is indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 6 2006

Wright Medical Technology, Inc.
C/o Mr. Brian J. Young
Senior Director, Regulatory Affairs
5677 Airline Road
Arlington, Tennessee 38002

Re: K053319
Trade/Device Name: ALLOMATRIX® Custom Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: resorbable calcium salt bone void filler
Regulatory Class: Class II
Product Code: MQV and MBP
Dated: January 9, 2006
Received: January 10, 2006

Dear Mr. Young:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson, M.S.
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K053319

Device Name: ALLOMATRIX® Custom Bone Void Filler

Indications for Use:

ALLOMATRIX® Custom is indicated only for bony voids or gaps that are not intrinsic to the stability of bony structure. ALLOMATRIX® Custom is intended to be gently packed into bony voids or gaps of the skeletal system as a bone graft extender (spine), and as a bone void filler in the extremities and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Prescription Use __X__ OR Over-The Counter Use ____
(Per21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K053319